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09/703,798		11/02/2000	Amanda Johanne Kiliaan	BO 44102 ACW	2164	
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ARLING	TON, VA	22202	1651			

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applica	ition No.	Applicant(s)			
Office Action Summary			,798	KILIAAN ET AL.			
			er	Art Unit			
		Ruth A.	Davis	1651			
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WHICHE - Extensio after SIX - If NO per - Failure to Any reply	RTENED STATUTORY PERIOD F EVER IS LONGER, FROM THE N ns of time may be available under the provisions (6) MONTHS from the mailing date of this commit riod for reply is specified above, the maximum so to reply within the set or extended period for reply to received by the Office later than three months atent term adjustment. See 37 CFR 1.704(b).	MAILING DATE OF to 37 CFR 1.136(a). In no nunication. Latutory period will apply and will, by statute, cause the a	THIS COMMUNICATION event, however, may a reply be tin will expire SIX (6) MONTHS from application to become ABANDONE	N. nely filed the mailing date of this o D (35 U.S.C. § 133).			
Status							
2a)∐ Th 3)∐ Si	esponsive to communication(s) filents action is FINAL . Ince this application is in condition osed in accordance with the pract	2b)⊠ This action is for allowance exce	s non-final. pt for formal matters, pro		e merits is		
Disposition	of Claims						
4a 5)	aim(s) 56-63,65-73,76,77,80 and) Of the above claim(s) is/a aim(s) is/are allowed. aim(s) 56-63,65-73,76-77,80-81 is/are objected to. aim(s) is/are objected to. aim(s) are subject to restrict Papers e specification is objected to by the drawing(s) filed on is/are objected to by the objected to aim(s) is/are objected to aim(s) is/are objected to aim(s) is/are objected to aim(s) is/are objected to aim(s) including objected to aim(s) including objected to aim(s) including objected to objected to aim(s) including objected to aim(s) including objected to objected to aim(s) including objected to objected to aim(s) including objected to objecte	are withdrawn from one solution and/or election and election and election and accepted or accepted or accepted the correction is required.	consideration. requirement. b) objected to by the label of the label	e 37 CFR 1.85(a). jected to. See 37 C			
Driority unc	ter 35 II S C & 119						
Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some color None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
2) Notice of 3) Informati	f References Cited (PTO-892) f Draftsperson's Patent Drawing Review (I ion Disclosure Statement(s) (PTO-1449 or o(s)/Mail Date		4) Interview Summary Paper No(s)/Mail D. 5) Notice of Informal F 6) Other:	ate	O-152)		

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DETAILED ACTION

Applicant's Request for Continued Examination, Affidavit, amendment and response filed on February 27, 2006 have been received and entered into the case. Claims 78 - 79 are canceled; claims 80 - 81 are added; claims 56 - 63, 65 - 73, 76 - 77 and 80 - 81 are pending and have been considered on the merits. The submitted declaration and all arguments have been fully considered. It is noted that the examiner of record has changed.

Claim Rejections - 35 USC § 112

- 1. Rejections under 35 U.S.C. 112, first paragraph, have been withdrawn.
- 2. Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 56, 59 – 62, 65, 69 – 70, 72 – 73, 76 – 77 and 80 – 81 are rejected under 35
 U.S.C. 103(a) as being unpatentable over Horrobin, Della Valle and Fugh-Berman.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (a) further comprises at least one of linoleic acid, alpha-linloenic acid, and optionally an omega 6 fatty acids selected from DHGLA and AA; wherein the ratio or EPA+DHA+DHGLA+AA to the total amount of linoleic and alpha-linoleic acid is above 0.4:1. The composition further comprises (d) citrates or citric acid; or (h) ginkgo biloba extract. Fraction (c) further comprises one of SAMe, choline, betaine or copper; the composition is a nutritional supplement. Specifically, the composition comprises at least 0.2 g phospholipids; 0.1 g phosphatidylserine; or at least 120 mg long chain fatty acids, 200 mg phospholipids, 200 micrograms folic acid, and 500 mg citrate.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA,

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DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

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Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

6. Claims 56 – 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Taiyo Fishery Co.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (b) comprising PC, PE and PS; and the weight ration of PC and PE to PS is from 0.5 – 20:1

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

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Taiyo Fishery Co teaches compositions of phosphatidylcholine and phosphatidylethanolamine for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

7. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Yu.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid

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selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises huperzine A.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Yu teaches compounds for treating dementia (abstract) wherein huperzine A is a representative compound (col.4 line 24-25).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of

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routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary

8. Claims 64 – 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Smith.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (c) further comprises folic acid and B6; or one of SAME, choline, betaine or copper.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

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Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col. 5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

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Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

9. Claims 65 – 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman and Hutterer.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Fraction (c) further comprises one of SAME, choline, betaine, or copper; or zinc and copper at a specified ratio.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

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Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

10. Claim 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della Valle, Fugh-Berman, Smith, Hutterer and Glick.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid

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selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine; and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. Specifically the composition comprises at least 20 mg EPA, 50 mg DHA, 50 mg AA, 200 mg phospholipids, 200 micrograms folic acid, 100 mg magnesium, 5 mg zinc, 2 mg vitamin B6, 2 micrograms vitamin B12 and 1g citrate.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Smith teaches compositions for treating Alzheimer's disease, comprising folic acid, vitamin B12 (abstract), betaine, and/or vitamin B6 (col.2 line 43-52).

Hutterer teaches compositions comprising choline, zinc and copper (abstract) in specific amounts and ratios (col.4 line 13-23) for treating Alzheimer's disease (abstract).

Glick teaches administering dietary supplements of magnesium for preventing and controlling dementia and memory loss (abstract, col.3).

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The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

11. Claims 67 – 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin, della valle, Fugh-Berman and Rabien.

Applicant claims a composition for treating and/or preventing dementia syndromes, cognitive degeneration or hearing loss, the composition comprising (a) one omega 3 fattty acid selected from EPA and DHA; (b) at least two different phospholipids selected from phosphatidylserine, phosphatidylinositol, phosphatidylcholine and phosphatidylethanolamine;

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and (c) at least one of folic acid, vitamin B12, B6, magnesium or zinc. The composition further comprises (f) one or more selected from carnitine, vitamin B1, B5 and coenzyme Q10; or (g) one or more antioxidants selected from vitamin C, E, lipoic acid, selenium salt and carotenoids.

Horrobin teaches compositions comprising essential fatty acids for treating dementia and Alzheimer's disease (abstract). Specifically, linoleic acid, alpha linoleic acid, DGLA, EPA, DHA, AA are combined in specific ratios and amounts (col.2 line 36-59). The composition further comprises citrates (claims, examples).

Della Valle teaches compositions comprising phosphatidylserine and phosphatidylethanolamine in specific ratios for treating dementia (abstract, col.5 line 44-59). Specifically, the compositions comprise 60 – 75% phosphatidylserine and 25 – 40% phosphatidylethanolamine (abstract).

Fugh-Berman teaches ginkgo biloba (p.715), vitamin B12, folate (p.721) and SAMe (p.722) for treating dementia, memory problems and cognitive function.

Rabien teaches compositions comprising alpha lipoic, panthothenic acid (vitamin B5) and vitamin E for treating Alzheimer's disease (abstract).

The above references do not teach all of the ingredients together in the same composition. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to combine the instant ingredients for their known benefit, as disclosed by the cited references above, since each is well known in the art for their claimed purpose. Although the references do not specifically teach the exact amounts and/or ratios, it would have been well within the purview of one of ordinary skill in the art to optimize such parameters as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in

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the art would have been motivated by the cited references to combine the instant ingredients with a reasonable expectation for successfully obtaining a composition for treating and/or preventing dementia syndromes and cognitive degeneration. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant argues that the claimed references do not teach each of the instant ingredients together in a single composition in the amounts and ratios claimed, alone or combined.

Applicant provides a declaration exhibiting evidence of the unexpected advantages and results of the various compositions. Applicant additionally argues that other supporting references do not remedy the deficiencies of Horrobin, Della Valle and Fugh-Berman.

However, these arguments and declaration fail to persuade because as evidenced by the cited references, each of the claimed ingredients were used in the art in compositions for treating dementia syndromes. Although they do not teach the claimed amounts or ratios, it would have been obvious to one of ordinary skill in the art to optimize the amounts of known active ingredients for the same purpose, as a matter of routine practice. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated to combine the

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instant ingredients and optimize the amounts, with a reasonable expectation for successfully obtaining a composition effective for treating dementia syndromes.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding the declaration, it is noted that the claims are not commensurate in scope with the Diet c of the declaration, which exhibits the activities presented and argued. The instant claims do not recite each and every element of the supplement demonstrated to have the unexpected advantage of improved capillary density, spatial memory qualities and MM performance.

Therefore the references stand rejected for the above reasons.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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April 28, 2006 AU 1651

> RUTH A. DAVIS PATENT EXAMINER

Rans